United States Patent Application For:

SYSTEM AND METHOD FOR MODIFYING UNDESIRABLE TISSUE

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority from **US Provisional Patent Application No. 60/436,327, filed December 23, 2002, entitled "NON-INVASIVE SYSTEM AND METHOD FOR REMOVAL OF ADIPOSE TISSUE"**, which is incorporated in its entirety herein by reference. This application also claims priority from **US Provisional Patent Application No. 60/436,334, filed December 23, 2002, entitled "METHOD FOR DESTROYING UNDESIRABLE TISSUE"**, which is incorporated in its entirety herein by reference.

[0002] This application is also a Continuation In Part (CIP) of **US Patent Application 10/642,037, filed 15 August, 2003, entitled "METHOD FOR DESTROYING UNDESIRABLE TISSUE"**, which is incorporated in its entirety herein by reference, which in turn claims benefit from **US Provisional Patent Application 60/403,973, filed on August 16, 2002 and entitled "Method of Destroying Undesirable Tissue"**, which is incorporated in its entirety herein by reference.

FIELD OF THE INVENTION

[0003] The present invention relates to methods and devices useful in modification, treatment, destruction, or removal of unwanted tissue.

BACKGROUND OF THE INVENTION

[0004] There are both physical and psychological reasons for treating and/or destroying undesirable tissue, for example, by destroying excess fat cells, modifying degraded tissue etc. The physical reasons may include prevention of heart disease, stroke, and diabetes, for example, by removal fatty cells. The psychological reasons may include

improvement of self-image, which may accompany treatments that may reduce excess tissue (e.g., fatty tissue, wrinkles, lesions etc.). Removing excess undesirable tissue has started playing an important role in medical and cosmetic procedures.

[0005] For example, adipose tissue, or "fat", is primarily located in the hypodermis, but may be found in other areas. The hypodermis is a layer of subcutaneous tissue located beneath the dermis. The cells are large compared to other cells in the outer layers of the body. They are generally round in shape, but may also be polyhedral when pressed together to form a "layer of fat". The nucleus of adipose cells is located near the cell membrane. Most of the volume of the cell is composed of a single droplet of liquid consisting of 90% triglycerides. There is little to no water inside a fat cell. Outside the fat cell is an area comprised of reticular fibers and a plexus of small capillaries. The capillaries transfer the triglycerides from the adipose cell to other cells when the body needs to generate energy.

[0006] One of the known methods of removing excess adipose tissue is liposuction. This is an invasive procedure in which the fat is destroyed mechanically and then extracted using a suction device.

[0007] An additional known method of removing excess adipose tissue includes using ultrasound to produce cavitation in fat cells (U.S. Patents Nos. 6,113,558 and 6,071,239). Ultrasound, however, is relatively expensive to administer, and it may be difficult to control the volume of treatment with ultrasound.

[0008] It would be highly advantageous to have a non-invasive method for treating or destroying unwanted tissue, which is relatively easy and cost effective to apply.

SUMMARY OF THE INVENTION

[0009] Embodiments of the present invention relate to devices, systems and methods of modifying and/or destroying undesirable human/animal tissue, for example using an electrical current conducted between electrodes to heat the undesirable cells to a temperature at which the cells may be modified or destroyed.

[0010] According to some embodiments of the present invention selected areas of tissue may be cooled to help prevent modification of these areas, while other areas that have not been cooled may be more readily modified. Some embodiments may include cooling the epidermis. Other embodiments may include cooling the dermis.

[0011] According to some embodiments of the present invention a lotion or gel may be applied to the epidermis to increase conductivity in the epidermis, thereby helping prevent modification of the epidermis.

[0012] In other embodiments a method is provided for destroying adipose tissue in the hypodermis of a human subject, by selecting an area of tissue for treatment, collecting the tissue between two electrodes, applying an electric current between the electrodes, and maintaining the current until the temperature of the adipose cells within the tissue reaches a level at which the adipose cells are destroyed.

[0013] According to some embodiments of the present invention, current supplied by an energy source may be AC current or DC current. Some embodiments of the present invention may include applying current in pulses and/or continuously.

[0014] In other embodiments a method is provided for destroying blood vessels in tissue that comprise port wine stains, rosacea, telangiectasias, and other vascular lesions.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] The principles and operation of the system, apparatus, and method according to the present invention may be better understood with reference to the drawings, and the following description, it being understood that these drawings are given for illustrative purposes only and are not meant to be limiting, wherein:

[0016] Fig. 1 is a schematic illustration of a system to perform cell modification according to embodiments of the present invention;

[0017] Figs. 2A-2B are cross section views of the system described in Fig. 1, according to some embodiments of the present invention;

[0018] Figs. 3A – 3B are charts illustrating the usage of various gels or lotions, according to an embodiment of the present invention;

[0019] Fig. 4 is a is a flowchart illustrating a method of modifying cells, according to some embodiments of the present invention;

[0020] Fig. 5 is a is a flowchart illustrating a method of modifying or destroying undesirable cells, according to some embodiments of the present invention; and

[0021] Fig. 6 is a graphical illustration of the effects of implementing the tissue modification method using the system of Fig. 1, according to some embodiments of the present invention.

[0022] It will be appreciated that for simplicity and clarity of illustration, elements shown in the drawings have not necessarily been drawn to scale. For example, the dimensions of some of the elements may be exaggerated relative to other elements for clarity. Further, where considered appropriate, reference numerals may be repeated among the drawings to indicate corresponding or analogous elements throughout the serial views.

DETAILED DESCRIPTION OF THE INVENTION

[0023] The following description is presented to enable one of ordinary skill in the art to make and use the invention as provided in the context of a particular application and its requirements. Various modifications to the described embodiments will be apparent to those with skill in the art, and the general principles defined herein may be applied to other embodiments. Therefore, the present invention is not intended to be limited to the particular embodiments shown and described, but is to be accorded the widest scope consistent with the principles and novel features herein disclosed. In other instances, well-known methods, procedures, and components have not been described in detail so as not to obscure the present invention.

[0024] In the following detailed description, numerous specific details are set forth in order to provide a thorough understanding of the present invention. However, it will be

understood by those skilled in the art that the present invention may be practiced without these specific details.

[0025] The phrase "adipose tissue" as used herein may encompass, for example, "fat", degraded tissue, collagen, tumors, or other undesirable tissue elements. Adipose tissue is used herein as an example of undesirable tissue, but it should be understood that embodiments of the present invention are applicable to other classes of tissue.

[0026] The electrical resistance of various tissues in animals/humans varies among tissue types. For example the electrical resistance of bone is much higher than the electrical resistance of muscle. The electrical resistance of fat is much higher than the resistance of the dermis and epidermis. An element within the human body that plays a dominant role in electrical resistance is water. Tissue with high water content has low electrical resistance. Tissues with low water content such as bone and fat have high electrical resistance.

[0027] According to some embodiments of the present invention, an electric current may be conducted through various types of tissues, thereby increasing the temperature in tissue with a higher resistance more than in tissue with a lower resistance. It is well known that elevating the temperature of a tissue can modify the tissue, therefore using the difference in temperature of the various tissues, modifications may be made to some tissues without significantly affecting other tissues. Various embodiments of the present invention may have other and different effects, and may rely on other and different bases.

[0028] In the case of adipose tissue, the electrical resistance of such tissue may be, for example, 10 to 14 times higher than that of other tissues in the outer layer of the human body. The lack of water in adipose cells may cause high electrical resistance. For example, adipose cells may include 90% triglycerides and approximately 10% water. Other cells in the outer layer of the human body may generally contain 70% or more water and hence have a low electrical resistance. The cells of the stratum cornea, the outer most layer of the epidermis, also have a low water content and hence a higher electrical resistance. Other suitable water levels may be observed.

[0029] Some embodiments of the present invention may enable modifying, treating, destroying and/or removing undesirable human/animal tissue using an electrical current to heat the undesirable cells to a temperature at which the cells may be modified or destroyed. Reference is now made to **Fig. 1**, which illustrates a system 10 for tissue modification according to some embodiments of the present invention. An energy source 11, for example, a DC or AC energy source, may provide an electric current to an electrical treatment device 12. The electric current may flow through wires 18 or alternative conductors to a plurality of electrodes, for example, electrodes 13 and/or 14, and may flow between electrodes 13 and 14 through tissue 16. In the case where AC is used, the electric current may first flow to one electrode, and then the field may reverse and flow to the other electrode. Current may be pulsed or continuous. Generation of current using frequencies below 100 KHz may be result in the current being felt by a patient using electrical treatment device 12. Generation of a current using frequencies above 10 MHz may result in current that may be difficult to control. Generation of current using frequencies between 100 KHz and 10 MHz may be used, according to some embodiments of the present invention, to modify, treat, destroy, and/or remove selected tissue. Other frequencies may be used, including frequencies below 100 KHz and above 10 MHz. The specific heat of adipose tissue may be approximately $3.7J/cm^3/C$. If 3.7 Joules of energy is deposited into 1 cubic centimeter of fat, it may raise its temperature approximately 1 degree Celsius (C). To destroy the adipose cell, the cell's temperature may need to be raised approximately 40 degrees C. This requires approximately 150 Joules per cm^3, which may be approximately equivalent to depositing 150 watts of energy in one second. Other temperature ranges and energy levels may be used.

[0030] Electrodes 13 and 14 may be located respectively on at least two sides of a tissue 16, for example, human or animal tissue, thereby conducting electric current through tissue 16. Electrodes of any suitable shapes and types may be used. Any suitable number of electrodes may be used, and the electrodes may be located in any suitable locations. In some embodiments electrodes that have smooth surface areas and rounded, squared or rectangular shapes may be used, to provide a current that is relatively easy to

control. Other suitable shapes or electrode types may be used. Of course, other suitable structures and dimensions may be used.

[0031] System 10 may include a conductive material 15 applied to the surface of tissue 16, for example, a lotion, gel, liquid suspension, or other suitable material. This additive may for example moisten the skin, and use the added moisture to increase the conductivity and decrease the resistance of the surface and/or surface area of the skin.

[0032] Reference is now made to **Fig. 2A**, which illustrates an apparatus 200 to enable modification or destruction of selected cells in the dermis or hypodermis layers in the skin. Apparatus 200 may, for example, establish an electrical pathway through a secured fold of skin 210 between a plurality of electrodes, for example, electrodes 220 and 230. The fold of skin 210 may be secured, for example, pinched or otherwise held by an electrical treatment device, for example, apparatus 200. In one embodiment apparatus 200 may include suction apparatus, which may be used for sucking, pinching, or otherwise maneuvering a fold of skin between two or more electrodes, such as electrodes 220 and 230. The suction apparatus may include, for example, an air pump attached via a hose to apparatus 200. The suction created by the air pump may pull the skin into the hand piece 260 of apparatus 200, for example, into the area indicated by 250, and between electrodes 220 and 230. In this way an appropriate amount of skin, which may include a target area 240, may be positioned and/or held in a chosen position for treatment. Hand piece 260 may include, for example, a holding mechanism to hold or secure the collected or pinched skin in place, for example, between the electrodes. For example, hand piece 260 of apparatus 200 may contact the skin 280, and suck up or otherwise secure a section or fold 210 of the skin and underlying tissue 290 into an area 250 of hand piece 260, between electrodes 220 and 230.

[0033] As can be seen with reference to **Fig. 2B**, when an electrical voltage is applied to electrode 220 and/or 230, a current may be conducted through the section of tissue 270, thereby modifying or destroying fat cells within area 270 of skin fold 210. The current may tend to or prefer to be conducted through the high resistance fat cells 290 because the path length is shorter and the cross-sectional area larger than the path "going

around" skin surface 280 from one electrode to the other, via the epidermis 282 or dermis 284.

[0034] According to some embodiments of the present invention electrodes 220 and/or 230 may be cooled, for example to protect the higher resistance stratum cornea, which is a layer of cells on the outermost layer of epidermis 282. Cooling may be implemented by cooling electrodes 220 and/or 230, or cooling the skin, using suitable cooling mechanisms known in the art of cooling.

[0035] A suction apparatus or other suitable skin securing apparatuses may be used, for example, to secure skin for hair removal, tattoo removal, scar modifications, and pigmentation changes etc.

[0036] According to some embodiments of the present invention the electrical conductivity of the epidermis may be increased by applying electrical conducting medium 15 (e.g., as shown in Fig. 1), for example, a liquid suspension, lotion, gel, liquid, cream, or other suitable conductive material to the surface of tissue 16. This addition to the skin surface may create, for example, a treatment zone that is more conducive of electric current than the naked skin, and may enable greater control over the effect of an electric current on the skin surface. Application of an electrical conducting medium to the epidermis may help control the variability of the epidermis's electrical resistance, for example, by reducing the epidermis's electrical resistance. According to some embodiments it may be desirable to reduce the electrical resistance of the epidermis to avoid excessive heating. Decreasing the electrical resistance of the outer layers of the epidermis, for example, may result in a more focused absorption of electrical energy into the target cells (e.g., area 240 of Fig. 2A), and correspondingly less peripheral damage to the epidermis.

[0037] Lotion, gels, and creams etc. are commonly used in medical procedures to improve the interface between treatment devices and treatment zones. For example ultrasonic gel may be used to provide an impedance match between an ultrasound transducer and a subject's epidermis. Cooling gel may be used for treatments involving light sources such as lasers and intensive pulse light sources. Electrically conducting gel may be used between the electrodes and the epidermis for EKG machines and

defibrillators. According to an embodiment of the present invention, various conducting or other suitable lotions or gels may be applied in such a manner that the lotion or gel may penetrate into the epidermis and for example provide enhanced conduction throughout the epidermis, in addition to the skin surface.

[0038] According to aspects of the invention, various electrical conducting mediums may be used, for example, to enhance electric conduction in the epidermis. The utility of a given conducting medium may be tested in various ways. For example, a voltage may be applied across a small volume of a lotion, and the voltage and corresponding current through the lotion measured. The electrical resistance of the lotion volume may for example be given by the ratio of current to voltage according to Ohm's Law: R = V/I. **Fig. 3A** shows the results of such a test, listing the relative resistances of a plurality of commercial and noncommercial lotions and gels. Other suitable lotions, gels, creams, suspensions etc. may be used.

[0039] Lotions or gels may also be tested by direct application to the epidermis, followed by a determination of the electrical conductivity of the treated area of skin. For example, the conductivity of the untreated skin in the area of the treatment zone may be measured. Lotions or gels may be applied to the area to be treated, and the conductivity may be measured again. Additionally or alternatively, an ultrasound device may be used for a predetermined period of time, to enhance the penetration of the applied lotion or gel. At a selected time period, the electrical resistance may be re-measured. The results of such conductivity tests for various exemplary lotions, with and without ultrasound enhancement, are shown in Fig. 3B; such results are given by way of examples only, and other suitable lotions or substances with other properties may be used.

[0040] As shown in Figs. 3A and 3B, a conducting lotion containing copper peptides (CP) may be highly effective in lowering the resistance of tissue. The copper in these lotions may provide an excellent conductor, and those skilled in the art will recognize that such lotions are already used to generate new collagen in human tissue. Copper peptide lotions may therefore be used to increase the electrical conductivity of the epidermis and/or to help generate new collagen. Other lotions that may be used may

include, for example, Vitamin C, retinal acid, Vitamin A, and other suitable elements. According to one embodiment of the present invention an ultrasound device may be used to enhance the penetration of the electrically conducting medium.

[0041] According to one embodiment of the present invention, system 10 may be used for, for example, removing wrinkles from skin. Wrinkles in human skin may partially result from degradation in the quality and/or quantity of collagen and elastin proteins in the dermis. Heating, for example, the dermis may trigger the generation of new collagen and/or elastin, resulting in the wrinkles being smoothed. Since these proteins reside in the dermis, which lies under the epidermis, it may be desirable that this heating takes place without damage to the epidermis. An epidermal conducting lotion or gel etc. may be applied to the skin surface, for example, before the application of electric current, to reduce the resistance of the epidermis and avoid incidental heating and resultant damage to the outer layers of the skin. As can be seen with reference to **Fig. 4**, at block 40 an electric current may be applied to an area to be treated, using, for example, electrical treatment device 12. At block 41 the electric current may heat the dermis therefore destroying, for example, degraded collagen and elastin proteins etc, or other elements. Additionally or alternatively, at block 42 the electric current may heat the dermis therefore generating, for example, production of collagen and elastin proteins etc., while the epidermis may be left relatively cool, and therefore remain substantially unaffected by the application of the electric current. In other embodiments similar procedures may be used to enable removal of hair, stimulation of hair growth, removal of capillaries, removal of pigmented lesions, removal of tattoos. Other steps or series of steps may be used.

[0042] Reference is now made to **Fig. 5**, which is a flow chart illustrating a method to modify or destroy undesirable tissue, according to some embodiments of the present invention. At block 50 an area of tissue may be selected for treatment. At block 51 the selected area of skin may be secured, for example, a fold of skin may be sucked, pinched or otherwise held by a suction apparatus, a hand etc. The fold of skin may include the epidermis, dermis, and/or hypodermis, any of which may include the target tissue, for example, an adipose layer, degraded protein layer, tumor, lesion etc. At block 52 two or more electrodes may be placed at the ends of the collected area of skin.

[0043] At block 53 selected areas of the tissue may be cooled, for example, to prevent or minimize modification to selected areas. For example, such selected areas may be cooled by cooling electrodes, or cooling the skin surface etc.

[0044] At block 54 a conducting lotion or gel may be applied to selected areas of tissue, for example, to enable the surface or surface area of the tissue to increase conductivity thereby preventing or minimizing modification of these areas due to the applied current. An ultrasonic apparatus, for example, may be used to absorb the lotion or gel in the epidermis.

[0045] At block 55 electric current may be applied to the fold of skin. The fold of skin placed between the electrodes may enable electricity to be conducted through a path comprising, for example, the epidermis, the dermis, the hypodermis, and then back through the dermis and the epidermis. In other embodiments the path may include the epidermis, the dermis, and may the extend back through the epidermis. Other suitable paths may be effected. In the case where the target tissue is in the hypodermis, the differing heat resistances of the skin layers may result, for example, in approximately 10 times more energy being deposited into adipose tissue elements in the hypodermis, as compared to other tissue elements in the epidermis and dermis. This may enable, for example, heating of adipose cells without significant heating of the cells in the epidermis and dermis.

[0046] At block 56 the electric current may be maintained, for example, until the temperature of the target cells (e.g., adipose cells) reaches a level at which the cell is modified or destroyed.

[0047] If adipose cells are heated to 60 degrees Celsius (C) or higher, the cells may be destroyed due to denaturation of the internal proteins. If the adipose cells are heated to 77 degrees C, the cell membrane may dissolve. The cells in the epidermis and dermis may be heated by approximately 4 degree C or less while the cells in the hypodermis are heated to 40 degrees C. This selectivity may enable destruction of the adipose cells without destroying the cells in the dermis and epidermis. Other temperatures may be used.

[0048] At block 57, in the case where cells have been destroyed, the cells may be extracted from the body using the body's natural cell replacement or other suitable methods. Any combination of the above steps may be implemented. Further, other steps or series of steps may be used.

[0049] According to some embodiments of the present invention, the lower resistance of the target tissue compared to the resistance of surrounding tissues may be used to modify or treat selected targets. Blood, for example, has a lower resistance than its surrounding tissues (blood has the highest conductivity of any entity in the body) for example, being approximately one half to one third the resistance of its surrounding tissue. By using a system, for example, similar to that described above with reference to Fig. 1, electric current applied to a tissue mass may, for example, be substantially conducted by the blood and not by the surrounding tissue. In cases such as port wine stains, rosacea, or telangiectasias, or other skin conditions where there is a plexus of blood vessels near the surface of the skin, an applied electric current may be better conducted by this plexus than by the surrounding tissue. This may result, for example, in preferential heating of the small capillaries in the plexus. With sufficient current, the blood may be heated to its coagulating temperature, for example, and may seal off selected blood vessels, for example, those comprising the vascular lesions. By sealing the vessels the dead cells of the plexus may be removed by the body.

[0050] Reference is now made to **Fig. 6**, which illustrates a graphic example of the effects an applied current may have on the epidermis, dermis, and hypodermis layers of selected tissue, using, for example, the system described in Fig. 1, according to an embodiment of the invention. As can be seen in Fig. 6, current applied to the a layer of tissue 60 folded between two or more electrodes, such as electrodes 61 and 62, may travel from, for example, electrode 61, through the cellular structure, the intercellular tissue, and the blood vessels etc., to electrode 62. The current may affect the area of tissue between the electrodes. In some embodiments, for example, where cooling may be applied to the dermis and/or epidermis, the heating resulting from the electric current may not effect or effect relatively little the areas of tissue that are relatively close to the epidermis and/or dermis. In such a case, the heat resulting from the electric current may be concentrated in a region of the tissue that may be relatively far from the epidermis

and/or dermis, for example, in area 65. Other areas may designated for cooling and/or heating

[0051] The foregoing description of the embodiments of the invention has been presented for the purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise form disclosed. It should be appreciated by persons skilled in the art that many modifications, variations, substitutions, changes, and equivalents are possible in light of the above teaching. It is, therefore, to be understood that the appended claims are intended to cover all such modifications and changes as fall within the true spirit of the invention.